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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631
7590 07/16/2010				
Lisa E. Alexander Sagres Discovery, Inc. c/o Chiron Corporation P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 07/16/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,920

Applicant(s)

MORRIS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are pending.
Claims 61, 71, 77-79, 81, 85 and 87-89 have been amended.
Claims 91-93 have been added.
Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 91 and 92 under 35 U.S.C. 102(b) as being anticipated by Qi et al. (Abstract from British Journal of Cancer 69(5): 903-910, 1994) is withdrawn in light of Applicants' arguments and evidence submitted April 28, 2010, see page 6 and corresponding sequence alignments.
4. The rejection of claims 91 and 92 under 35 U.S.C. 102(b) as being anticipated by Saeki et al. (Cancer Research 52: 3467-3473, June 15, 1992) is

withdrawn in light of Applicants' arguments and evidence submitted April 28, 2010, see page 7 and corresponding sequence alignments.

5. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 86, 91 and 92 under 35 U.S.C. 102(e) as being anticipated by Cassart/ U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003) is withdrawn in light of Applicants' arguments and evidence submitted April 28, 2010, see page 7 and corresponding sequence alignments.

Claim Rejections - 35 USC § 103

6. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. 103(a) as being unpatentable over Qi et al. (Abstract from British Journal of Cancer 69(5): 903-910, 1994), and further in view of Cassart/ U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003) and Olsen/ U.S. Patent 6,852,506 B1 (filed April 11, 1997) is withdrawn in light of Applicants' arguments and evidence submitted April 28, 2010, see page 7 and corresponding sequence alignments.

7. The rejection of Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. 103(a) as being unpatentable over Cassart et al./ U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003), and further in view of Olsen/ U.S. Patent 6,852,506 B1 (filed April 11,

1997) is withdrawn in light of Applicants' arguments and evidence submitted April 28, 2010, see page 7 and corresponding sequence alignments.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicants assert "...whether or no CR1 is present in both cancerous and non-cancerous tissues is not relevant to the issue of enablement of the claimed methods" and "there is no requirement that CR1 is present in one of the tissues and not expressed at all in the other", see Remarks submitted April 28, 2010, bridging paragraph of pages 5 and 6. Applicants conclude arguments citing "CR1 expression that is 'ubiquitous' does not preclude differential expression levels between cancerous and non cancerous tissues" and "the Examiner has not met the initial burden to establish a reasonable basis to question the enablement", see Remarks, page 6. These arguments have been carefully considered, but found unpersuasive.

The previous Action mailed February 3, 2010 made clear while the Office does not require astonishing results there must be some valid amount of direction or guidance, as well as presence or absence of working examples presented in the specification that would enable one skilled in the art to perform the method as presented in the recited claims. Applicants' claims read on determining whether or not a patient has breast cancer dependent upon differential expression of CR1. Applicants seem to be in agreement with the Examiner in regard to the characterization of the Zhang sequence (Zhang et al./ U.S. Patent Application Publication number US 2007/0099251 A1 (published May 3, 2007) has sequence 14579), wherein it is expressed in both normal (non cancerous), as well as cancerous tissues. The Examiner is clear that the claims do not require a resolute endpoint, where "...CR1 is present in one of the tissues and not expressed at all in the other as noted by Applicants", see last full sentence of page 5, Remarks. The independent claims do not establish a 'cutoff' and while further dependent claims denote "...the expression product in the sample is altered....relative to the control" there is mention of whether one of ordinary skill in the art is to observe an increase or decrease in the expression products. Applicants' claims read on implementing CR1 (SEQ ID NO: 1320) as a biomarker essential for validating whether or not clinical material obtained from subjects is diseased or not. Prior to the successful application of a biomarker its predictive value must be confirmed and established. Applicants' specification does not exemplify examples supporting that at the

time of the claimed invention was made that Applicants were able to discriminately diagnose any cancers given using CR1 as a valid biomarker. Based on the analysis and the teachings presented above it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Double Patenting

10. The provisional rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of copending Application No. 10/573,332 (filed April 6, 2007) is maintained.

Applicants "...request deferral of this ground of rejection until there is an indication of allowable subject matter in one or both applications", see Remarks, page 8. This point of view has been carefully considered and the rejection is maintained given neither application at this point in prosecution has allowable subject matter.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday between the hours of 8 am to 8 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
09 July 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643